

Supplementary table 1. Definitions and grading of 197 health conditions evaluated in the ALL-STAR study according to the St Jude modified version ¹ of the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 ² . Health conditions without available definitions from CTCAE v4.03 or the St Jude modified version are inserted with references if readily available and otherwise marked in <i>italic</i> .			
AUDITORY-HEARING			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Cholesteatoma	<p>Definition: A mass formed by the keratinizing squamous epithelium in the middle ear and/or mastoid, subepithelial connective tissue and by the progressive accumulation of keratin debris with/without surrounding inflammatory reaction.³</p> <p>Grading source: St Jude modification of CTCAEv4.03 Ear and labyrinth disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Hearing loss	<p>Definition: A disorder characterized by partial or complete loss of the ability to detect or understand sounds resulting from damage to ear structures. Includes sensorineural, conductive and mixed hearing loss.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Ear and labyrinth disorders: Hearing impaired.</p> <p>St Jude Modified Chang Ototoxicity Grading Scale:</p> <p>Chang KW, Chinosornvatana N. Practical grading system for evaluating cisplatin ototoxicity in children. J Clin Oncol 2010;28(10):1788-95.</p>	<p>1: ≥ 40 dB at any frequency 6-12 kHz (Chang 1a); > 20 and < 40 dB at 4kHz (Chang 1b)</p> <p>2: ≥ 40 dB at 4 kHz and above (Chang 2a); > 20 and < 40 dB at any frequency <4kHz (Chang 2b)</p> <p>3: ≥ 40 dB at 2 or 3 kHz and above</p> <p>4: ≥ 40 dB at 1 kHz and above</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Tinnitus	<p>Definition: A disorder characterized by noise in the ears, such as ringing, buzzing, roaring or clicking</p> <p>Grading source: CTCAEv4.03 Ear and labyrinth disorders: Tinnitus</p>	<p>1: Mild symptoms; intervention not Indicated</p> <p>2: Moderate symptoms; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation

Vertigo	<p>Definition: A disorder characterized by a sensation as if the external world were revolving around the patient (objective vertigo) or as if he himself were revolving in space (subjective vertigo). Includes: Meniere's</p> <p>Grading source: CTCAEv4.03 Ear and labyrinth disorders: Vertigo</p>	<p>1: Mild symptoms; intervention not Indicated 2: Moderate symptoms; limiting instrumental ADL 3: Severe symptoms; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
CARDIOVASCULAR			
Health condition	Definition and Grading source	Grading	
Aortic root aneurysm	<p>Definition: A permanent localized dilation of the aortic artery having at least a 50% increase in diameter compared to the expected.⁴</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated (aortic root ≥ 3.5 cm to < 4 cm) 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL (aortic root ≥ 4 cm) 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Arteriovenous malformation	<p>Definition: <i>An abnormal connection between arteries and veins, bypassing the capillary system.</i></p> <p>Grading source: CTCAE v4.03 Cardiac Disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Atrioventricular heart block	<p>Definition: Includes: 1st degree (PR > 200 msec), 2nd degree, Mobitz I, 2nd degree, Mobitz II, 3rd degree (complete) Bundle branch block, QRS > 120 ms, Stokes-Adams Syndrome</p> <p>Grading source: CTCAE v4.03 Cardiac Disorders: AV Block first degree (grades 1&2); AV block complete; Mobitz (type) II AV block; Mobitz type I (grades 3&4)</p>	<p>1: Asymptomatic; intervention not indicated 2: Symptomatic; non-urgent medical intervention indicated 3: Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker) 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation - Electrocardiogram</p>

Bradycardia, sinus	<p>Definition: A disorder characterized by a dysrhythmia with a heart rate less than 50 beats per minute that originates in the sinus node</p> <p>Grading source St Jude modification of CTCAE v4.03 Cardiac Disorders: Sinus bradycardia</p>	<p>1: Asymptomatic; intervention not indicated 2: Symptomatic; medical intervention indicated 3: Severe; medically significant, medical intervention indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation - Electrocardiogram</p>
Cardiopulmonary fitness, reduced	<p>Definition: The component of physiologic fitness relating to the ability of the cardiopulmonary system to supply oxygen during sustained physical activity. Reported as number of standard deviations (SD) from the expected mean, based on values from healthy controls.</p> <p>Grading source: ALL-STAR research team</p>	<p>1: Symptomatic; shortness of breath during ADL and moderate physical activity perceived by the patient but not evident on physical exam 2: Symptomatic; reduced aerobic performance evident on physical exam; limiting instrumental ADL 3: Impaired aerobic performance limiting self-care ADL; < -1.96 SD of age and sex specific healthy control values 4: Not applicable 5: Not applicable</p>	<p>- Cardiopulmonary fitness test</p>
Conduction abnormalities	<p>Definition: Includes: Sick Sinus Syndrome, Wolff-Parkinson-White syndrome</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Conduction disorder</p>	<p>1: Asymptomatic or mild symptoms; intervention not indicated 2: Moderate symptoms; non-urgent intervention indicated 3: Severe symptoms; intervention indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation - Electrocardiogram</p>
Congestive heart failure	<p>Definition: A disorder characterized by the inability of the heart to pump blood at an adequate volume to meet tissue metabolic requirements, or, the ability to do so only at an elevation in the filling pressure.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Heart failure</p>	<p>1: Asymptomatic with laboratory (e.g. BNP) or cardiac imaging abnormalities (NYHA I) 2: Symptoms with mild to moderate activity or exertion (NYHA II) 3: Severe with symptoms at rest or with minimal activity or exertion; intervention indicated (NYHA III) 4: Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical hemodynamic support (NYHA IV) 5: Death</p>	<p>- Questionnaire and medical record validation - n-terminal pro brain natriuretic peptide (BNP) - Electrocardiogram - Speckle tracking echocardiography - Cardiac MRI -</p>

Coronary artery disease	<p>Definition: A disorder characterized by the inability of the heart to pump blood at an adequate volume to meet tissue metabolic requirements, or, the ability to do so only at an elevation in the filling pressure. Includes myocardial infarction.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Myocardial infarction</p>	<ol style="list-style-type: none"> 1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Mild symptoms and cardiac enzymes minimally abnormal and no evidence of ischemic electrocardiogram changes 3: Severe symptoms; cardiac enzymes abnormal; hemodynamically stable; electrocardiogram changes consistent with infarction (Q waves) 4: Life-threatening consequences; hemodynamically unstable (CABG or angioplasty) 5: Death 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Troponin-T - Electrocardiogram
Cor pulmonale (right heart failure)	<p>Definition: A disorder characterized by impairment of right ventricular function associated with low ejection fraction and a decrease in motility of the right ventricular wall</p> <p>Grading source CTCAE v4.03 Cardiac Disorders: Right ventricular dysfunction</p>	<ol style="list-style-type: none"> 1: Asymptomatic with laboratory (e.g., BNP) or cardiac imaging abnormalities 2: Symptoms with mild to moderate activity or exertion 3: Severe symptoms, associated with hypoxia, right heart failure; oxygen indicated 4: Life-threatening consequences; urgent intervention indicated (e.g., ventricular assist device); heart transplant indicated 5: Death 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - n-terminal pro brain natriuretic peptide - Speckle tracking echocardiography - Cardiac MRI
Dysrhythmia	<p>Definition: A disorder characterized by a dysrhythmia originating above the ventricles. Includes: atrial fibrillation, atrial flutter, SVA, SVT, PAT; ventricular arrhythmia, and lethal arrhythmia requiring defibrillation.</p> <p>Grading source: CTCAE v4.03 Cardiac Disorders: Atrial fibrillation</p>	<ol style="list-style-type: none"> 1: Asymptomatic, intervention not indicated 2: Non-urgent medical intervention indicated 3: Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker), or ablation 4: Life-threatening consequences; urgent intervention indicated 5: Death 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Electrocardiogram
Heart valve disorder	<p>Definition: Disorders characterized by a defect in heart valve function or structure.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Aortic valve disease; mitral valve disease; pulmonary valve disease; tricuspid valve disease</p>	<ol style="list-style-type: none"> 1: Asymptomatic valvular thickening/calcifications with or without mild valvular regurgitation or stenosis by imaging 2: Asymptomatic; moderate regurgitation or stenosis by imaging 3: Symptomatic; severe regurgitation or stenosis by imaging; symptoms controlled with medical intervention 4: Life-threatening consequences; urgent intervention indicated (e.g., valve replacement, valvuloplasty) 5: Death 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Speckle tracking echocardiography - Cardiac MRI

High total cholesterol	<p>Definition: Higher than normal levels of cholesterol in a blood specimen</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Investigations: Cholesterol high</p> <p>ALL-STAR modification: Units reported in SI-units, (100mg/dL = 2.59mmol/dL)⁵.</p>	<p>1: >200 mg/dL - 300 mg/dL (>5.18 mmol/L–7.77 mmol/L)</p> <p>2: >300 - 400 mg/dL (>7.77 mmol/L –10.36 mmol/L); treatment with one lipid lowering agent</p> <p>3: >400 - 500 mg/dL (>10.36 mmol/L –12.95 mmol/L); treatment with ≥2 lipid lowering agent</p> <p>4: >500 mg/dL (>12.95 mmol/L)</p> <p>5: Not applicable</p>		<p>- Questionnaire and medical record validation</p> <p>- Cholesterol level</p>
Hypertension (from resting blood pressure)	<p>Definition: A disorder characterized by a pathological increase in blood pressure; a repeatedly elevation in the blood pressure</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Vascular Disorders: Hypertension</p> <p>Limits according to National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. Pediatrics. 2004;114(2 Suppl 4th Report):555.</p>	Adult	Pediatric	<p>- Questionnaire and medical record validation</p> <p>- Blood pressure measurement</p>
		1: Prehypertension (systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg)	1: Prehypertension (systolic and/or diastolic BP ≥ 90th percentile but < 95th percentile for gender, age and height, or if in adolescents BP exceeds 120/80 mmHg even if <90th percentile)	
		2: Stage 1 hypertension (systolic BP 140 - 159 mm Hg or diastolic BP 90 - 99 mm Hg); medical intervention indicated or initiated; recurrent or persistent (≥24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg if previously WNL; monotherapy indicated or initiated	2: Stage 1 hypertension (systolic and/or diastolic BP between the 95th percentile and 5 mmHg above the 99th percentile for gender, age and height, or if in adolescents the BP exceeds 140/90 mmHg even <95th percentile); monotherapy indicated or initiated	
		3: Stage 2 hypertension (systolic BP ≥160 mm Hg or diastolic BP ≥100 mm Hg); medical intervention indicated; more than one drug or more intensive therapy than previously used indicated or initiated	3: Stage 2 hypertension (systolic and/or diastolic BP ≥99th percentile plus 5 mmHg for gender, age, and height); more than one drug or more intensive therapy than previously used indicated or initiated	
		4: Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated	4: Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated	
		5: Death	5: Death	

Hypertriglyceridemia	<p>Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of triglyceride concentration in the blood</p> <p>Grading source St Jude modification of CTCAE v4.03 Metabolism and Nutrition Disorders: Hypertriglyceridemia</p> <p>ALL-STAR modification: Units reported as SI-units, (100mg/dL = 1.13mmol/L)⁵</p>	<p>1: 150 mg/dL - 300 mg/dL (1.70 mmol/L–3.39 mmol/L)</p> <p>2: >300 mg/dL - 500 mg/dL (>3.39 mmol/L – 5.65 mmol/L); treatment with one lipid lowering agent</p> <p>3: >500 mg/dL - 1000 mg/dL (>5.65 mmol/L – 11.3mmol/L); treatment with ≥2 lipid lowering agents</p> <p>4: >1000 mg/dL (>11,3mmol/L); life-threatening consequences</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Triglyceride level
Left ventricular systolic dysfunction	<p>Definition: A disorder characterized by failure of the left ventricle to produce adequate output despite an increase in distending pressure and in end-diastolic volume and reduced ejection fraction. Clinical manifestations may include dyspnea, orthopnea, and other signs and symptoms of pulmonary congestion and edema. Includes cardiomyopathy</p> <p>Grading source: St Jude modification of CTCAE v4.03 Investigations: Ejection fraction decreased (grades 2&3) Left ventricular systolic dysfunction (grade 4)</p>	<p>1: Not applicable</p> <p>2: Resting EF < 50-40%; 10 - 19% absolute drop from baseline</p> <p>3: Resting EF 39-20%; >20% absolute drop from baseline; medication indicated or initiated</p> <p>4: Resting EF<20%; refractory or poorly controlled heart failure due to drop in ejection fraction; on medical management; intervention such as ventricular assist device, intravenous vasopressor support, or heart transplant indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Speckle tracking echocardiography - Cardiac MRI
Pericarditis	<p>Definition: A disorder characterized by irritation to the layers of the pericardium (the protective sac around the heart).</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Pericarditis</p>	<p>1: Asymptomatic, electrocardiogram or physical findings (e.g., rub) consistent with pericarditis</p> <p>2: Symptomatic pericarditis (e.g., chest pain)</p> <p>3: Pericarditis with physiologic consequences (e.g., pericardial constriction)</p> <p>4: Life-threatening consequences; urgent intervention indicated (e.g., cardiac tamponade)</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Electrocardiogram

Prolonged QTcorrected (QTc) interval	<p>Definition: A finding of a cardiac dysrhythmia characterized by an abnormally long corrected QT interval</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Investigations: Prolonged QTc interval</p>	<p>1: QTc 460 - 480 ms (men); 470-480 ms (women)</p> <p>2: QTc 481 - 500 ms</p> <p>3: QTc \geq 501 ms on \geq two separate electrocardiograms</p> <p>4: QTc \geq 501 or >60 ms change from baseline and Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia</p> <p>5: Not applicable</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Electrocardiogram
Pulmonary hypertension	<p>Definition: A disorder characterized by an increase in pressure within the pulmonary circulation due to lung or heart disorder</p> <p>Grading source: CTCAE v4.03</p> <p>Respiratory, thoracic, and mediastinal disorders: Pulmonary hypertension</p>	<p>1: Minimal dyspnea; findings on physical exam or other evaluation</p> <p>2: Moderate dyspnea, cough; requiring evaluation by cardiac catheterization and medical intervention</p> <p>3: Severe symptoms, associated with hypoxemia, right heart failure; oxygen indicated</p> <p>4: Life-threatening airway consequences; urgent intervention indicated (e.g., tracheotomy or intubation)</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Speckle tracking echocardiography
Raynaud phenomenon	<p>Definition: A clinical disorder consisting of recurrent, long-lasting, and episodic vasospasm of the fingers and toes (rarer in tongue, nose, ears, nipples) often associated with exposure to cold.⁶</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Vascular Disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire, COMPASS31 and medical record validation
Right ventricular systolic dysfunction	<p>Definition: A disorder characterized by impairment of right ventricular function associated with low ejection fraction and a decrease in motility of the right ventricular wall</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Cardiac Disorders: Right ventricular dysfunction</p>	<p>1: Asymptomatic cardiac imaging abnormalities</p> <p>2: Symptoms with mild to moderate activity or exertion</p> <p>3: Severe symptoms, associated with hypoxia, right heart failure; oxygen indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated (e.g., ventricular assist device); heart transplant indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Speckle tracking echocardiography - Cardiac MRI

Tachycardia, sinus	<p>Definition: A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute for adults and greater than 110 beats per minute for children that originates in the sinus node</p> <p>Grading source: St Jude modification of CTCAE v4.03 Cardiac Disorders: Sinus tachycardia</p>	<p>1: Asymptomatic, intervention not indicated 2: Symptomatic; non-urgent medical intervention indicated 3: Urgent medical intervention indicated 4: Not applicable 5: Not applicable</p>	<p>- Questionnaire and medical record validation - Electrocardiogram</p>
Thromboembolic event	<p>Definition: A disorder characterized by occlusion of a vessel by a thrombus that has migrated from a distal site via the blood stream.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Vascular Disorders: Thromboembolic event</p>	<p>1: Venous thrombosis (e.g., superficial thrombosis) 2: Venous thrombosis (e.g., uncomplicated deep vein thrombosis), medical intervention indicated 3: Thrombosis (e.g., non-embolic cardiac mural [arterial] thrombus), medical intervention indicated 4: Life-threatening (e.g., cerebrovascular event, arterial insufficiency); hemodynamic or neurologic instability; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation</p>
Vascular disease	<p>Definition: Stenosis/occlusion of vessel other than coronary or cerebral vessels, e.g., carotid, subclavian.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Vascular Disorders Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation</p>
ENDOCRINE			
Health condition	Definition and Grading source	Grading	Data Grading source
Abnormal glucose metabolism	<p>Definition: A disorder characterized by an inability to properly metabolize glucose. Includes impaired fasting glucose, insulin resistance with impaired glucose tolerance, diabetes mellitus.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Metabolism and nutrition disorders: Glucose intolerance</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; pharmacologic intervention not indicated or initiated (e.g. dietary modification) 2: Symptomatic; oral agent indicated or initiated 3: Severe symptoms; insulin indicated or initiated 4: Life threatening consequences, urgent intervention indicated or initiated 5: Death</p>	<p>- Questionnaire and medical record validation - Fasting-glucose - HOMA-IR</p>

Adrenal insufficiency	<p>Definition: A disorder that occurs when the adrenal cortex does not produce enough of the hormone cortisol and in some cases, the hormone aldosterone. It may be due to a disorder of the adrenal cortex as in Addison's disease or primary adrenal insufficiency.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Endocrine disorders: Adrenal insufficiency</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention indicated during periods of stress</p> <p>2: Moderate symptoms; daily maintenance indicated (i.e. am cortisol < 5 mcg/dL) or initiated</p> <p>3: Severe symptoms; hospitalization indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Adult growth hormone deficiency	<p>Definition: A finding based on laboratory test results that indicate abnormal levels of growth hormone in a biological specimen</p> <p>Grading source: St Jude modification of CTCAE v4.03 Investigations: Growth hormone abnormal</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated (IGF-1 z-score < -2 in isolation or abnormal dynamic test with decision not to pursue treatment)</p> <p>2: Symptomatic; medical intervention indicated; limiting instrumental ADL</p> <p>3: Not applicable</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Childhood growth hormone deficiency	<p>Definition: A finding based on laboratory test results that indicate abnormal levels of growth hormone in a biological specimen</p> <p>Grading source: St Jude modification of CTCAE v4.03 Investigations: Growth hormone abnormal</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated (abnormal dynamic test with decision not to pursue treatment)</p> <p>2: Symptomatic; medical intervention indicated; limiting instrumental ADL</p> <p>3: Not applicable</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Diabetes insipidus	<p>Definition: A form of polyuria–polydipsia syndrome characterized by hypotonic polyuria and polydipsia.⁷</p> <p>Grading source: St Jude modification of CTCAE v4.03. Endocrine disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Growth hormone excess	<p>Definition: A finding based on laboratory test results that indicate abnormal levels of growth hormone in a biological specimen</p> <p>Grading source: St Jude modification of CTCAE v4.03. Investigations: Growth hormone abnormal</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL</p> <p>3: Death Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Hyperparathyroidism	<p>Definition: A disorder characterized by an increase in production of parathyroid hormone by the parathyroid glands. This results in hypercalcemia (abnormally high levels of calcium in the blood).</p> <p>Grading source: St Jude modification of CTCAE v4.03. Endocrine disorders: Hyperparathyroidism</p>	<p>1: Mild symptoms; intervention not indicated</p> <p>2: Moderate symptoms; medical intervention indicated or initiated</p> <p>3: Not applicable</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Parathyroid hormone</p> <p>- Ionized calcium</p>
Hyperprolactinemia	<p>Definition: A disorder of mineral metabolism due to excessive secretion of parathyroid hormone from one or more of the four parathyroid glands.⁸</p> <p>Grading source: St Jude modification of CTCAE v4.03. Endocrine disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Hyperthyroidism	<p>Definition: A disorder characterized by excessive levels of thyroid hormone in the body. Common causes include an overactive thyroid gland or thyroid hormone overdose</p> <p>Grading source: St Jude modification of CTCAE v4.03 Endocrine disorders: Hyperthyroidism</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; thyroid suppression indicated or initiated; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL; hospitalization indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Thyroid stimulating hormone</p> <p>- Triiodothyronine</p>

Hypoparathyroidism	<p>Definition: A disorder characterized by a decrease in production of parathyroid hormone by the parathyroid glands.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Endocrine disorders: Hypoparathyroidism</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate symptoms; medical intervention indicated or initiated</p> <p>3: Severe symptoms; medical intervention or hospitalization indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Parathyroid hormone - Ionized calcium
Hypothyroidism	<p>Definition: A disorder characterized by a decrease in production of thyroid hormone by the thyroid gland. Includes compensated hypothyroidism.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Endocrine disorders: Hypothyroidism</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated (compensated hypothyroidism)</p> <p>2: Symptomatic; thyroid replacement indicated or initiated; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL; hospitalization indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Thyroid stimulating hormone - Triiodothyronine
Overweight/Obesity	<p>Definition: A disorder characterized by having a high amount of body fat. Grading source for < 20 years: Criteria per Centers for Disease Control and Prevention guidelines</p> <p>Grading source: St Jude modification of CTCAE v4.03 Metabolism and nutrition disorders: Obesity</p> <p>ALL-STAR modification: Pediatric Grading source according to National, Danish norm material⁹.</p>	<p>For age ≥ 20 years</p> <p>1: Not applicable</p> <p>2: BMI 25 - 29.9 kg/m²</p> <p>3: BMI 30 - 39.9 kg/m²</p> <p>4: BMI ≥ 40 kg/m²</p> <p>5: Not applicable</p>	<p>For age 2 - <20 years</p> <p>1: Not applicable</p> <p>2: BMI ≥ 85thile <95thile</p> <p>3: BMI ≥ 95thile</p> <p>4: Not applicable</p> <p>5: Not applicable</p> <p>ALL-STAR modification:</p> <p>1: Not applicable</p> <p>2: BMI > +1 < +2 standard deviations (84.1%-97.7%)</p> <p>3: BMI > +2 standard deviations (>97.7%)</p> <p>4,5: NA</p> <ul style="list-style-type: none"> - Questionnaire and medical record validation - Weight - Height

Sarcopenic obesity	<p>Definition High body fat percentage (BF%) and/or high android fat percentage (AF%) and/or high android/gynoid fat distribution ratio (AG ratio).</p> <p>Grading source: ALL-STAR research team</p> <p>Standard deviations used for grading are based on results from matched ALL-STAR controls and on the following available sources:</p> <p><u>BF% in children:</u> Wohlfahrt-Veje et al. Body fat throughout childhood in 2647 healthy Danish children: Agreement of BMI, waist circumference, skinfolds with dual X-ray absorptiometry. Eur J Clin Nutr. 2014;68(6):664–70.</p> <p><u>AF% in children:</u> Tinggaard J et al. Anthropometry, DXA, and leptin reflect subcutaneous but not visceral abdominal adipose tissue on MRI in 197 healthy adolescents. Pediatr Res. 2017 Oct 1;82(4):620–8.</p> <p><u>BF% and AG ratio in adults:</u> Miazgowski T et al. Visceral fat reference values derived from healthy European men and women aged 20–30 years using GE Healthcare dual-energy x-ray absorptiometry. PLoS One. 2017 Jul 1;12(7).</p>	<p>1: Not applicable</p> <p>2: BF% > +1 standard deviations (SD) < +2 SD OR AG > +1 standard deviations (SD) < +2 SD</p> <p>3: BF% > +2 SD OR AG > +2SD</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>1: Not applicable</p> <p>2: BF% > +1 standard deviations (SD) < +2 SD OR AF% > +1 standard deviations (SD) < +2 SD</p> <p>3: BF% > +2 SD OR AF% > +2SD</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- DEXA body composition scans
Syndrome of inappropriate antidiuretic hormone secretion	<p>Definition: A syndrome characterized by hyponatremia and renal salt loss, unrelated to either renal or adrenal disease, but attributed to overexpansion of body fluids resulting from inappropriate secretion of antidiuretic hormone (ADH).¹⁰</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Endocrine disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>		- Questionnaire and medical record validation

Underweight	<p>Definition: Low weight compared to the expected for age and height</p> <p>Grading source: St Jude introduced category. Grading source: Criteria per Centers for Disease Control and Prevention guidelines</p> <p>ALL-STAR modification: BMI limit expressed as number of standard deviations from the expected mean, based on national Danish reference material⁹</p>	<p>For age ≥ 20 years</p> <p>1: Not applicable 2: BMI < 18.5 kg/m² 3: Not applicable 4: Not applicable 5: Not applicable</p>	<p>For age 2 < 20 years</p> <p>1: Not applicable 2: BMI $< 5^{\text{th}}$ile ($< -2SD = < 2.3\%$ile) 3: Not applicable 4: Not applicable 5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Weight</p> <p>- Height</p>
GASTROINTESTINAL				
Health condition	Definition and Grading source	Grading		Data Grading source
Bowel perforation	<p>Definition: A disorder characterized by a rupture in the small intestine wall.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Small intestinal perforation</p>	<p>1: Not applicable 2: Symptomatic; medical intervention indicated 3: Severe symptoms; elective operative intervention indicated 4: Life-threatening consequences; urgent operative intervention indicated 5: Death</p>		- Questionnaire and medical record validation
Celiac disease	<p>Definition: An autoimmune disorder occurring in genetically predisposed individuals who develop an immune reaction to gluten.¹¹</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>		- Questionnaire and medical record validation
Constipation	<p>Definition: A disorder characterized by irregular and infrequent or difficult evacuation of the bowels.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Constipation</p>	<p>1: Not applicable 2: Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL 3: Obstipation with manual evacuation indicated; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>		- Questionnaire, COMPASS31 and medical record validation

Dysphagia	<p>Definition: A disorder characterized by difficulty in swallowing</p> <p>Grading source: CTCAEv4.03</p> <p>Gastrointestinal disorders: Dysphagia</p>	<p>1: Symptomatic, able to eat regular diet</p> <p>2: Symptomatic and altered eating or swallowing</p> <p>3: Severely altered eating or swallowing; tube feeding or TPN or hospitalization indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Enterocolitis	<p>Definition: A disorder characterized by inflammation of the small and large intestines. Includes: ileitis, typhlitis, colitis, enterocolitis, diverticulitis, Crohn's disease, ulcerative colitis.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Gastrointestinal disorders: Enterocolitis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Abdominal pain; mucus or blood in stool</p> <p>3: Severe or persistent abdominal pain; fever; ileus; peritoneal signs</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Esophageal varices	<p>Definition: A disorder characterized by bleeding from esophageal varices</p> <p>Grading source: CTCAEv4.03</p> <p>Gastrointestinal disorders: Esophageal varices hemorrhage</p>	<p>1: Not applicable</p> <p>2: Self-limited; intervention not indicated</p> <p>3: Transfusion, radiologic, endoscopic, or elective operative intervention indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Esophagitis	<p>Definition: A disorder characterized by inflammation of the esophageal wall.</p> <p>Grading source: CTCAEv4.03</p> <p>Gastrointestinal disorders: Esophagitis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; altered eating/swallowing; oral supplements indicated</p> <p>3: Severely altered eating/swallowing; tube feeding, TPN or hospitalization indicated</p> <p>4: Life-threatening consequences; urgent operative intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Fecal incontinence	<p>Definition: A disorder characterized by inability to control the escape of stool from the rectum.</p> <p>Grading source: CTCAEv4.03</p> <p>Gastrointestinal disorders: Fecal incontinence</p>	<p>1: Occasional use of pads required</p> <p>2: Daily use of pads required</p> <p>3: Severe symptoms; elective operative intervention indicated</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire, COMPASS31 and medical record validation

Gastritis/duodenitis	<p>Definition: A disorder characterized by inflammation of the stomach</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Gastritis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; altered GI function; medical intervention indicated</p> <p>3: Severely altered eating or gastric function; TPN or hospitalization indicated</p> <p>4: Life-threatening consequences; urgent operative intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Gastroesophageal reflux disease	<p>Definition: A disorder characterized by reflux of the gastric and/or duodenal contents into the distal esophagus. It is chronic in nature and usually caused by incompetence of the lower esophageal sphincter and may result in injury to the esophageal mucosal. Symptoms include heartburn and acid indigestion.</p> <p>Grading source: CTCAEv4.03 Gastrointestinal disorders: Gastroesophageal reflux disease</p>	<p>1: Mild symptoms; intervention not indicated</p> <p>2: Moderate symptoms; medical intervention indicated</p> <p>3: Severe symptoms; surgical intervention indicated</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Gastrointestinal fistulas	<p>Definition: A disorder characterized by an abnormal communication between any part of the gastrointestinal system and another organ or anatomic site</p> <p>Grading source: CTCAEv4.03 Gastrointestinal disorders: Gastrointestinal fistula</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; altered GI function</p> <p>3: Severely altered GI function; tube feeding, TPN or hospitalization indicated; elective operative intervention indicated</p> <p>4: Life-threatening consequences; urgent operative intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Gastrointestinal hemorrhage	<p>Definition: A disorder characterized by bleeding from the upper/lower gastrointestinal tract (oral cavity, pharynx, esophagus, and stomach, small intestine, large intestine, and anus).</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Upper/Lower gastrointestinal hemorrhage</p>	<p>1: Mild; intervention not indicated</p> <p>2: Moderate symptoms; medical intervention or minor cauterization indicated</p> <p>3: Transfusion; invasive intervention indicated (e.g. radiologic, endoscopic, or elective operative interventions)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Gastrointestinal necrosis	<p>Definition: A disorder characterized by a necrotic process occurring in the gastric/intestinal wall.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Gastric necrosis</p>	<p>1: Not applicable 2: Not applicable 3: Inability to aliment adequately by GI tract; radiologic, endoscopic, or operative intervention indicated 4: Life-threatening consequences; urgent operative intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Gastrointestinal obstruction	<p>Definition: A disorder characterized by blockage of the normal flow of the intestinal contents.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Small intestinal obstruction</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Symptomatic; altered GI function; limiting instrumental ADL 3: Hospitalization indicated; elective operative intervention indicated; limiting self-care ADL; disabling 4: Life-threatening consequences; urgent operative intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Gastrointestinal strictures	<p>Definition: A disorder characterized by a narrowing of the lumen of the esophagus/stomach/intestines</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Esophageal stenosis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Symptomatic; altered GI function 3: Severely altered GI function; tube feeding; hospitalization indicated; elective operative intervention indicated 4: Life-threatening consequences; urgent operative intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Gastrointestinal ulcer	<p>Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the stomach/intestines</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Gastric ulcer</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADLs 3: Severely altered GI function; TPN indicated; invasive intervention indicated (e.g. elective operative or endoscopic intervention); limiting self-care ADL; disabling 4: Life-threatening consequences; urgent operative intervention indicated 5: Death</p>	- Questionnaire and medical record validation

Gastroparesis syndrome	<p>Definition: A chronic disorder characterized by delayed emptying of the stomach after eating, in the absence of any mechanical obstruction.¹²</p> <p>Grading source: CTCAEv4.03 Gastrointestinal disorders: Gastroparesis</p>	<p>1: Mild nausea, early satiety and bloating, able to maintain caloric intake on regular diet</p> <p>2: Moderate symptoms; able to maintain nutrition with dietary and lifestyle modifications; may need pharmacologic intervention</p> <p>3: Weight loss; refractory to medical intervention; unable to maintain nutrition orally</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire, COMPASS31, and medical record validation
Malabsorption syndrome	<p>Definition: A disorder characterized by inadequate absorption of nutrients in the small intestine. Symptoms include abdominal marked discomfort, bloating and diarrhea</p> <p>Grading source CTCAEv4.03 Gastrointestinal disorders: Malabsorption</p>	<p>1: Not applicable</p> <p>2: Altered diet; oral intervention Indicated</p> <p>3: Inability to aliment adequately; TPN indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Pancreatic insufficiency	<p>Definition: A finding based on laboratory test results that indicate a decrease in levels of pancreatic enzymes in a biological specimen.</p> <p>Grading source: CTCAEv4.03 Investigations: Pancreatic enzymes decreased</p>	<p>1: <LLN and asymptomatic</p> <p>2: Increase in stool frequency, bulk, or odor; steatorrhea</p> <p>3: Sequelae of absorption deficiency</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Fecal elastase</p>
Pancreatitis	<p>Definition: A disorder characterized by inflammation of the pancreas</p> <p>Grading source: CTCAEv4.03 Gastrointestinal disorders: Pancreatitis</p>	<p>1: Not applicable</p> <p>2: Enzyme elevation or radiologic findings only</p> <p>3: Severe pain; vomiting; medical intervention indicated (e.g., analgesia, nutritional support)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Amylase</p> <p>- Lipase</p> <p>- Ultrasound examination of pancreas</p>
Proctitis	<p>Definition: A disorder characterized by inflammation of the rectum.</p> <p>Grading source: CTCAEv4.03 Gastrointestinal disorders: Proctitis</p>	<p>1: Rectal discomfort, intervention not indicated</p> <p>2: Symptoms (e.g., rectal discomfort, passing blood or mucus); medical intervention indicated; limiting instrumental ADL</p> <p>3: Severe symptoms; fecal urgency or stool incontinence; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

HEPATOBIILIARY			
Health condition	Definition and Grading source	Grading	Data Grading source
Cholecystitis/ Cholelithiasis	<p>Definition: A disorder characterized by inflammation involving the gallbladder. It may be associated with the presence of gallstones</p> <p>Grading source: St Jude modification of CTCAEv4.03 Hepatobiliary disorders: Cholecystitis</p>	<p>1: Not applicable 2: Symptomatic; medical intervention indicated 3: Severe symptoms; invasive intervention indicated (e.g. radiologic, endoscopic or elective operative intervention) 4: Life-threatening consequences; urgent operative intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation</p>
Fibrosis/Cirrhosis	<p>Definition: A condition resulting from liver injury leading to necroinflammation and fibrogenesis.¹³ Includes patients with Hepatitis B and Hepatitis C induced cirrhosis.</p> <p>Grading source: Category and grading according to St Jude</p> <p>ALL-STAR modification: ultrasound shear wave elastography (USWE) added</p>	<p>1: Not applicable 2: Not applicable 3: Compensated USWE proven or biopsy proven fibrosis/cirrhosis (e.g. asymptomatic thrombocytopenia) 4: Decompensated USWE proven or biopsy proven fibrosis/cirrhosis (e.g., coagulopathy, encephalopathy, coma, variceal hemorrhage) 5: Death</p>	<p>- Questionnaire and medical record validation - Liver enzymes, INR, albumin, platelets - Hepatic ultrasound including USWE and evaluation of spleen</p>
Hepatic failure	<p>Definition: A disorder characterized by the inability of the liver to metabolize chemicals in the body. Laboratory test results reveal abnormal plasma levels of ammonia, bilirubin, lactic dehydrogenase, and alkaline phosphatase.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Gastrointestinal disorders: Hepatic failure</p>	<p>1: Not applicable 2: Not applicable 3: Asterixis; mild encephalopathy; limiting self-care ADL 4: Moderate to severe encephalopathy; coma; life threatening consequences; requiring liver transplantation 5: Death</p>	<p>- Questionnaire and medical record validation - Liver enzymes, INR, albumin, platelets, bilirubin, LDH</p>

Hepatopathy	<p>Definition: A finding based on laboratory test results that indicate an increase in the level of aspartate aminotransferase (AST or SGOT) and alanine aminotransferase (AST or SGPT) in a blood specimen</p> <p>Grading source: CTCAEv4.03</p> <p>Investigations: Alanine and aspartate aminotransferase Increased</p>	<p>1: >ULN - 3.0 x ULN 2: >3.0 - 5.0 x ULN 3: >5.0 - 20.0 x ULN 4: >20.0 x ULN 5: Not applicable</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Liver enzymes
Portal hypertension	<p>Definition: A disorder characterized by an increase in blood pressure in the portal venous system.</p> <p>Grading source: CTCAEv4.03</p> <p>Gastrointestinal disorders: Portal hypertension</p>	<p>1: Not applicable 2: Decreased portal vein flow 3: Reversal/retrograde portal vein flow; associated with varices and/or ascites 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Hepatic ultrasound with Doppler
Veno-occlusive disease of liver (Sinusoidal obstructive syndrome)	<p>Definition: A syndrome characterized by at least three of five, otherwise unexplained, criteria: hepatomegaly; hyperbilirubinemia more than UNL; ascites; weight gain of at least 5%; and thrombocytopenia.¹⁴</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Hepatobiliary disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Weight - Bilirubin, platelets - Abdominal and hepatic ultrasound

HEMATOLOGIC			
Health condition	Definition and Grading source	Grading	Data Grading source
Anemia	<p>Definition: A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Blood and lymphatic disorders: Anemia</p> <p>ALL-STAR modification: Units reported as SI-units (100 g/dL = 62 mmol/L)</p>	<p>1: Hgb <LLN by sex/age-appropriate standards but ≥ 10.0 g/dL (≥ 6.2 mmol/L)</p> <p>2: Hgb <10.0 - 8.0 g/dL (<6.2 mmol/L–4.96 mmol/L)</p> <p>3: Hgb <8.0 g/dL (< 4.96 mmol/L); transfusion indicated < 4.96 mmol/L</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Hemoglobin
Coagulopathy	<p>Definition: Includes: disseminated intravascular coagulation, thrombotic thrombocytopenic purpura, hemolytic uremic syndrome, acquired von Willebrand disease, etc.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Blood and lymphatic disorders: Disseminated intravascular Coagulation</p>	<p>1: Not applicable</p> <p>2: Not applicable</p> <p>3: Laboratory findings and bleeding</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Hematologic blood samples

Iron overload	<p>Definition: Iron overload is defined as excess stores of iron in the body. Excess iron is deposited in organs throughout the body. The most notable organs with iron deposition are the liver, heart, and endocrine glands. Resulting symptoms and disease are related to specific organ damage.¹⁵</p> <p>Grading source: Category and grading according to St Jude</p> <p>ALL-STAR modification: Ferritin limit of 1000 ng/mL added to grade 2 since this value is often used as indicative of therapy in hematologic patients.¹⁶</p>	<ol style="list-style-type: none"> 1: Tissue iron overload confirmed by imaging (e.g., T2*) or biopsy; intervention not indicated 2: Tissue iron overload confirmed by imaging (e.g., T2*) or biopsy; phlebotomy or oral chelation therapy indicated or initiated or ferritin > 1000 ng/mL 3: Tissue iron overload confirmed by imaging (e.g., T2*) or biopsy; intravenous or subcutaneous chelation therapy indicated or initiated 4: Life-threatening consequences; urgent intervention indicated or initiated; liver transplantation indicated or completed 5: Death 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Ferritin - Cardiac MRI T2*
Neutropenia	<p>Definition: A finding based on laboratory test results that indicate a decrease in number of neutrophils in a blood specimen.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Investigations: Neutrophil count decreased</p> <p>ALL-STAR modification: Units reported as SI units. (1000 unit/mm³ = 1x10⁻⁹/L)</p>	<ol style="list-style-type: none"> 1: <1500 - 1000/mm³ (<1.5*10⁻⁹/L –1*10⁻⁹/L) 2: <1000 - 500/mm³ (<1*10⁻⁹/L –0.5*10⁻⁹/L) 3: <500/mm³ (<0.5*10⁻⁹/L) 4: Not applicable 5: Not applicable 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Neutrophil count
Polycythemia	<p>Definition: A finding based on laboratory test results that indicate increased levels of hemoglobin in a biological specimen</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Investigations: Hemoglobin increased</p> <p>ALL-STAR modification: Units reported as SI units. (100 g/dL = 62mmol/L)</p>	<ol style="list-style-type: none"> 1: Increase in >0 - 2 g/dL (>0–1.24 mmol/L) ULN or above baseline if baseline is above ULN 2: Increase in >2 - 4 g/dL (>1.24–2.48 mmol/L) above ULN or above baseline if baseline is above ULN; requiring phlebotomy or other medical intervention. 3: Increase in >4 g/dL (>2.48 mmol/L) above ULN or above baseline if baseline is above ULN 4: Not applicable 5: Not applicable 	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Hemoglobin

Thrombocytopenia	<p>Definition: Definition: A finding based on laboratory test results that indicate a decrease in number of platelets in a blood specimen.</p> <p>Grading source: CTCAEv4.03</p> <p>Investigations: Platelet count decreased</p> <p>ALL-STAR modification: Units reported as SI units. (1000 unit/mm3 = $1 \times 10^9/L$)</p>	<p>1: Platelets <LLN - 75,000/mm3 ($75 \times 10^9/L$)</p> <p>2: <75,000 - 50,000/mm3 ($<75-50 \times 10^9/L$)</p> <p>3: <50,000 - 25,000/mm3 ($<50-25 \times 10^9/L$)</p> <p>4: <25,000/mm3 ($<25 \times 10^9/L$)</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Platelet count</p>
Thrombocytosis	<p>Definition: <i>Elevated number of platelets in the blood.</i></p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Blood and lymphatic disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Platelet count</p>
IMMUNOLOGIC			
Health condition	Definition and Grading source	Grading	Data Grading source
Autoimmune disorders	<p>Definition: A disorder resulting from loss of function or tissue destruction of an organ or multiple organs, arising from humoral or cellular immune responses of the individual to his own tissue constituents. (Includes: sarcoidosis, collagen vascular diseases -- rheumatoid arthritis, systemic lupus erythematosus, scleroderma, dermatomyositis, polyarteritis nodosa)</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Immune system disorders: Autoimmune disorder</p>	<p>1: Asymptomatic; serologic or other evidence of autoimmune reaction, with normal organ function; intervention not indicated</p> <p>2: Evidence of autoimmune reaction involving a nonessential organ or function (e.g., hypothyroidism)</p> <p>3: Autoimmune reactions involving major organ (e.g., colitis, anemia, myocarditis, kidney)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>

Graft-versus-host disease	<p>Definition: A complication of allogeneic hematopoietic stem cell transplantation involving inflammation, cell-mediated immunity, humoral immunity, and fibrosis and resulting in a syndrome of variable clinical features resembling autoimmune and other immunologic disorders.¹⁷</p> <p>Grading source: St Jude modification of CTCAEv4.03 Immune system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated or initiated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated or initiated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Immunodeficiency	<p>Definition: Includes: hypogammaglobulinemia IgA deficiency, immunodeficiency NOT due to HIV or other infectious/neoplastic processes</p> <p>Grading source: St Jude modification of CTCAEv4.03 Immune system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated or initiated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated (e.g. IVIG) or initiated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Immunoglobulin levels</p>
INFECTIONS			
Health condition	Definition and Grading source	Grading	
Bronchial/lung infections. Chronic and/or recurrent	<p>Definition: A disorder characterized by an infectious process involving the lungs. Defined as 3 infections in 6 months.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Infections and infestations: Lung infection</p>	<p>1: Not applicable</p> <p>2: Moderate symptoms; oral intervention indicated or initiated (e.g., antibiotic, antifungal, antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic, endoscopic, or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Endocarditis infective	<p>Definition: A disorder characterized by an infectious process involving the endocardial layer of the heart.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Infections and infestations: Endocarditis infective</p>	<p>1: Not applicable</p> <p>2: Not applicable</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention)</p> <p>3: Life-threatening consequences; urgent intervention indicated</p> <p>4: Death</p>	<p>- Questionnaire and medical record validation</p>

Gastrointestinal infection	<p>Definition: A disorder characterized by an infectious process involving the gastrointestinal tract. Includes: appendicitis diverticulitis, typhlitis, esophagitis, gastritis, and enterocolitis.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Infections and infestations: Small intestine infection</p>	<p>1: Not applicable 2: Moderate symptoms; oral intervention indicated or initiated (e.g., antibiotic, antifungal, antiviral) 3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic, endoscopic, or operative intervention) 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation</p>
Genitourinary infection	<p>Definition: A disorder characterized by an infectious process involving the urinary tract, most commonly the bladder and the urethra</p> <p>Grading source: St Jude modification of CTCAEv4.03 Infections and infestations: Urinary tract infection</p>	<p>1: Not applicable 2: Oral intervention indicated or initiated (e.g., oral or topical antibiotic, antifungal, antiviral) 3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic, endoscopic, or operative intervention) 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation - Urine leucocytes and nitrite</p>
Hepatitis B, chronic	<p>Definition: A disorder characterized by a viral pathologic process involving the liver parenchyma.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Infections and infestations: Hepatitis viral</p>	<p>1: Asymptomatic 2: Asymptomatic but treated with antiviral therapy 3: Symptomatic liver dysfunction; fibrosis by biopsy; compensated cirrhosis; hospitalization or prolongation of existing hospitalization indicated 4: Decompensated liver function (e.g., coagulopathy, encephalopathy, coma, variceal hemorrhage) 5: Death</p>	<p>- Questionnaire and medical record validation - HBV antibodies</p>
Hepatitis C, chronic	<p>Definition: A disorder characterized by a viral pathologic process involving the liver parenchyma.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Infections and infestations: Hepatitis viral</p>	<p>1: Asymptomatic 2: Asymptomatic but treated with antiviral therapy 3: Symptomatic liver dysfunction; fibrosis by biopsy; compensated cirrhosis; hospitalization or prolongation of existing hospitalization indicated 4: Decompensated liver function (e.g., coagulopathy, encephalopathy, coma, variceal hemorrhage) 5: Death</p>	<p>- Questionnaire and medical record validation - HCV antibodies</p>

HIV infection	<p>Definition: <i>Infection with human immunodeficiency virus.</i></p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated or initiated (e.g., HAART therapy); limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening, including sequelae of opportunistic infection; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Lymphatic infection	<p>Definition: A disorder characterized by an infectious process involving the lymph nodes</p> <p>Grading source St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Lymph gland infection</p>	<p>1: Not applicable</p> <p>2: Localized; local intervention indicated or initiated (e.g., topical antibiotic, antifungal, or antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Meningoencephalitis	<p>Definition: A disorder characterized by acute inflammation of the meninges of the brain and/or spinal cord.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Meningitis</p>	<p>1: Not applicable</p> <p>2: Not applicable</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention); focal neurologic deficit</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Osteomyelitis	<p>Definition: A disorder characterized by an infectious process involving the bones.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Bone infection</p>	<p>1: Not applicable</p> <p>2: Not applicable</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Otitis media, chronic/recurrent	<p>Definition: A disorder characterized by an infectious process involving the middle ear. Defined as 3 infections in 6 months.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Otitis media</p>	<p>1: Not applicable</p> <p>2: Localized; local intervention indicated or initiated (e.g., topical antibiotic, antifungal, or antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Pelvic inflammatory disease	<p>Definition: A disorder characterized by an infectious process involving the pelvic cavity</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Pelvic infection</p>	<p>1: Not applicable</p> <p>2: Moderate symptoms; oral intervention indicated or initiated (e.g., antibiotic, antifungal, antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Pharyngitis/tonsillitis, chronic/recurrent	<p>Definition: A disorder characterized by inflammation of the throat. Defined as 3 infections in 6 months</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Pharyngitis</p> <p>ALL-STAR modification: Includes also tonsillectomy due to recurring infections</p>	<p>1: Not applicable</p> <p>2: Localized; local intervention indicated or initiated (e.g., topical antibiotic, antifungal, or antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic, endoscopic, or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Sinusitis, chronic/recurrent	<p>Definition: A disorder characterized by an infectious process involving the mucous membranes of the paranasal sinuses. Defined as 3 infections in 6 months.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Sinusitis</p> <p>ALL-STAR modification: Chronic is defined as lasting more than 12 weeks</p>	<p>1: Not applicable</p> <p>2: Localized; local intervention indicated or initiated (e.g., topical antibiotic, antifungal, or antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic, endoscopic, or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Soft tissue infection	<p>Definition: A disorder characterized by an infectious process involving soft tissues.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Infections and infestations: Soft tissue infection</p>	<p>1: Not applicable</p> <p>2: Moderate symptoms; oral intervention indicated or initiated (e.g., antibiotic, antifungal, antiviral)</p> <p>3: IV antibiotic, antifungal, or antiviral intervention indicated or initiated; invasive intervention indicated (e.g., radiologic or operative intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
MUSCULOSKELETAL			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Amputation	<p>Definition: <i>Removal of a limb.</i></p> <p>Grading source: Category and grading according to St Jude and</p> <p>ICD-9-CM Diagnosis and Procedure Codes: Abbreviated and Full Code Titles. Centers for Medicare & Medicaid Services <https://www.cms.gov/medicare/coding/icd9providerdiagnosticcodes/codes.html#></p> <p>ALL-STAR modification: IDC-10 Version 2019. https://icd.who.int/browse10/2019/en></p>	<p>1: Partial ostectomy or other bone repair</p> <p>2: Amputation below ankle or below elbow; revision of amputation</p> <p>3: Total ostectomy; upper extremity amputation above elbow or higher; lower extremity amputation above ankle or higher</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Arthralgia	<p>Definition: A disorder characterized by a sensation of marked discomfort in a joint</p> <p>Grading source: CTCAEv4.03 Musculoskeletal & connective tissue disorders: Arthralgia</p>	<p>1: Mild pain</p> <p>2: Moderate pain; limiting instrumental ADL</p> <p>3: Severe pain; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Arthritis	<p>Definition: A disorder characterized by inflammation involving a joint.</p> <p>Grading source: CTCAEv4.03 Musculoskeletal & connective tissue disorders: Arthritis</p>	<p>1: Mild pain with inflammation, erythema, or joint swelling</p> <p>2: Moderate pain associated with signs of inflammation, erythema, or joint swelling; limiting instrumental ADL</p> <p>3: Severe pain associated with signs of inflammation, erythema, or joint swelling; irreversible joint damage; disabling; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation

Bone mineral density deficit	<p>Definition: A disorder characterized by reduced bone mass, with a decrease in cortical thickness and in the number and size of the trabeculae of cancellous bone (but normal chemical composition), resulting in increased fracture incidence.</p> <p>Grading source St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Osteoporosis</p> <p>-and-</p> <p>New Grading source (Pediatric) International Society of Clinical Densitometry</p>	<p>Adults</p> <p>1: Radiologic evidence of osteoporosis or Bone Mineral Density (BMD) t-score -1 to -2.5 (osteopenia); no loss of height or intervention indicated; 2: BMD t-score <-2.5; loss of height <2 cm; anti-osteoporotic therapy indicated or initiated; therapy to improve BMD indicated or initiated; limiting instrumental ADL; 3: Loss of height >=2 cm; hospitalization indicated; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	<p>Pediatric</p> <p>1: Radiologic evidence of low BMD with z score of ≤-2.0 and no history of significant fractures 2: Low BMD (z-score ≤-2.0) and significant fracture history (defined as a long bone fracture of the lower extremity, vertebral compression, 2 or more long bone fracture of the upper extremities); therapy to improve BMD indicated or initiated 3: Limiting self-care ADL 4: Not applicable 5: Not applicable</p>	<ul style="list-style-type: none">- Questionnaire and medical record validation- DXA bone scan
Hernia	<p>Definition: Includes: abdominal, umbilical, ventral, inguinal, femoral, etc.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<ul style="list-style-type: none">- Questionnaire and medical record validation	
Intervertebral disc disorder	<p>Definition: Includes: disc degeneration, disc herniation</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<ul style="list-style-type: none">- Questionnaire and medical record validation	

Kyphosis	<p>Definition: A disorder characterized by an abnormal increase in the curvature of the thoracic portion of the spine.</p> <p>Grading source St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Kyphosis</p>	<p>1: Not applicable 2: Moderate accentuation; limiting instrumental ADL 3: Severe accentuation; operative intervention indicated; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Limb length discrepancy	<p>Definition: A disorder characterized by of a discrepancy between the lengths of the lower or upper extremities</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Unequal limb length</p>	<p>1: Not applicable 2: Moderate length discrepancy 2-5 cm; shoe lift indicated; limiting instrumental ADL 3: Severe length discrepancy >5 cm; limiting self-care ADL; disabling; operative intervention indicated 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Osteonecrosis	<p>Definition: A disorder characterized by necrotic changes in the bone tissue due to interruption of blood supply. Most often affecting the epiphysis of the long bones, the necrotic changes result in the collapse and the destruction of the bone structure.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Avascular necrosis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Symptomatic; medical intervention indicated (e.g., analgesics, anti-inflammatory); limiting instrumental ADL 3: Severe symptoms; limiting self-care ADL; elective operative intervention indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Palatal defects, acquired	<p>Definition: <i>Palatal defect not present at birth</i></p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation

Scoliosis	<p>Definition: A disorder characterized by a malformed, lateral curvature of the spine.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Scoliosis</p>	<p>1: > 8 and <15 degrees; clinically undetectable</p> <p>2: >=15 - 30 degrees; visible by forward flexion; limiting instrumental ADL</p> <p>3: >=30 degrees; scapular prominence in forward flexion; operative intervention indicated; limiting self-care ADL; disabling</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Skeletal spine disorder	<p>Definition: Includes: spondylitis, spondylolisthesis, spondylomalacia, spondylosis</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Slipped capital femoral epiphysis	<p>Definition: Posterior and inferior displacement of the femoral epiphysis relative to the femoral head and neck.¹⁸</p> <p>Grading source: St Jude modification of CTCAEv4.03 Musculoskeletal & connective tissue disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
ORAL-DENTAL			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Dental caries	<p>Definition: A biofilm-mediated, sugar-driven, multifactorial disease that results in the phasic demineralization and remineralization of dental hard tissues.¹⁹</p> <p>Grading source: ALL-STAR research team. Decayed Missed Filled (DMF)-teeth/surfaces scoring system and International Caries Detection and Assessment System (ICDAS).¹⁹</p>	<p>1: No clinical visible carious lesions.</p> <p>2: Initial caries, non-cavitated (may be white, yellow/brown); dental intervention needed including preventive measures.</p> <p>3: Carious lesion in enamel with cavity; dental restoration needed.</p> <p>4: Shadow from dentin with or without localized enamel breakdown; dental treatment needed.</p> <p>5: Distinct and extensive distinct cavity with visible dentine; dental restoration, and/or endodontic treatment, or extraction; disabling.</p>	<p>- Questionnaire and medical record validation</p> <p>- Dental evaluation</p>

Dental erosion	<p>Definition: A condition characterized by loss or wear of dental hard tissue by acids and not caused by bacteria. May be caused by intrinsic (e.g., acid reflux and excessive vomiting) and/or extrinsic (e.g., diet) factors.²⁰</p> <p>Grading source: ALL-STAR research team. Basic Erosive Wear Examination (BEWE)-score.²¹</p>	<p>1: No surface loss 2: Initial loss of enamel surface texture 3: Distinct defect, hard tissue loss (dentine) less than 50% of the surface area 4: Hard tissue loss more than 50% of the surface area. Disabling. 5: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Dental evaluation
Gingivitis	<p>Definition: Inflammation of the gums includes gingival redness, edema, bleeding on slight provocation or spontaneously, and swelling with loss of stippling. Difficulty in chewing. Gingivitis can lead to periodontitis.²²⁻²⁴</p> <p>Grading source: ALL-STAR research team. Plaque index and gingival index.^{22,23}</p>	<p>1: No plaque, No inflammation 2: A film of plaque adhering to the free gingival margin and adjacent area of the tooth. Mild inflammation. 3: Moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin, which can be seen with the naked eye. Moderate inflammation with bleeding on probing. 4: Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. Severe inflammation and tendency to spontaneous bleeding. Dental intervention needed. 5: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Dental evaluation
Periodontitis	<p>Definition: A chronic multifactorial inflammatory disease associated with dysbiotic plaque biofilms and characterized by progressive destruction of the tooth-supporting apparatus. Its primary features include the loss of periodontal tissue support, manifested through clinical attachment loss (CAL) and radiographically assessed alveolar bone loss, presence of periodontal pocketing and gingival bleeding.²⁵</p> <p>Grading source: ALL-STAR research team. Plaque index, gingival index, periodontal pocket depth assessment.^{22,23,25}</p>	<p>1: Mild to moderate periodontitis 2: Moderate to severe periodontitis Based on bleeding on probing scores and probing pocket depths > 5 mm etc. 3: Tooth loss due to periodontitis 4: All stages require dental intervention, from preventive measure to oral rehabilitation. 5: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Dental/periodontal evaluation

Acute sialadenitis	<p>Definition: Acute inflammation of salivary glands, usually the major ones, and most commonly the parotid gland, followed by submandibular and sublingual glands. May be induced by infection, medication autoimmune or metabolic disease.²⁶</p> <p>Grading source: ALL-STAR research team</p>	<p>1: Not applicable 2: Painful swelling reddened skin, edema of the cheek and neck; medical intervention indicated. 3: Low-grade fever, malaise, elevated ESR, CRP, leukocytosis, purulent exudate from duct orifice; urgent intervention indicated. 4: Life-threatening consequences; urgent intervention indicated. 5: Not applicable</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Orofacial evaluation including inspection and palpation, sialometry
Chronic sialadenitis	<p>Definition Chronic inflammation of salivary glands, usually the major ones, and most commonly the parotid gland, followed by submandibular and sublingual glands. May be induced by infection, medication autoimmune or metabolic disease.²⁶</p> <p>Grading source: ALL-STAR research team</p>	<p>1: Mild pain and swelling. 2: Moderate pain and swelling/recurrent swellings, related to meals, often unilateral 3: reddened duct orifice and decreased salivary flow. 4: Severe pain and secondary infection; medical intervention indicated. 5: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Orofacial evaluation including inspection and palpation, sialometry
Salivary gland dysfunction	<p>Definition: A condition characterized by changes in salivary flow, amount, and/or quality of saliva produced. Most commonly hyposalivation and xerostomia.²⁷</p> <p>Grading source: ALL-STAR research team. Measurement of whole saliva flow rates (sialometry); Xerostomia Inventory (XI); Visual Analogue Scale; Clinical Oral Dryness Score (CODS).²⁸</p>	<p>1: Mild symptoms of xerostomia; normal unstimulated (UWS, 0.3-0.5 ml/min) and chewing-stimulated whole saliva (SWS, 1-3 ml/min) flow rates. 2: Mild-moderate symptoms and low secretors (UWS 0.2 ml/min). 3: Severe symptoms and hyposalivation (UWS \leq 0.1 ml/min, and SWS \leq 0.70 ml/min). 4: Persistent hyposalivation with clinical consequences including dental caries, dental erosion, gingivitis, mucosal ulcerations and infections, difficulties chewing, swallowing, taste and speech etc.; dental and medical intervention; impact on food intake; disabling. 5: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Clinical oral examination, sialometry

Temporomandibular joint disorder	<p>Definition: Collection of conditions characterized by pain in the jaw muscles and/ or temporomandibular joint (TMJ) as well as surrounding structures, functional limitations in the TMJ or sounds (cracking, crepitation) from the TMJ. May be transient, recurrent or chronic.²⁹</p> <p>Grading source: ALL-STAR research team. Assessment of jaw muscles (palpation of the temporalis and masseter muscles) and joint pain (palpation and upon function); jaw movements (i.e., opening, lateral, and protrusive), functional and morphological dental occlusion.²⁹</p>	<p>1: Mild orofacial pain/TMD myalgia and or arthralgia. 2: Moderate orofacial pain/TMD myalgia and/or arthralgia. 3: Severe orofacial pain/TMD myalgia and/or arthralgia; medical and dental intervention needed. 4: Extensive TMD; may require surgical intervention. 5: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Orofacial and dental evaluation
Dental maldevelopment	<p>Definition: A disorder characterized by pathological processes of the teeth occurring during tooth development. Includes: adontia, hypodontia, microdontia, root stunting, enamel demineralization/ decalcification etc.</p> <p>Grading source: CTCAEv4.03 Gastrointestinal disorders: Tooth development disorder</p>	<p>1: Asymptomatic; hypoplasia of teeth or enamel. 2: Impairment correctable with oral surgery. 3: Malformation with impairment not surgically correctable; disabling. 3: Not applicable. 4: Not applicable.</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Orofacial and dental evaluation
NEUROLOGIC			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Autonomic dysfunction	<p>Definition: Disorder in the autonomic nerve system. Includes Horner's syndrome</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<ul style="list-style-type: none"> - Questionnaire, COMPASS31, and medical record validation - Heart rate variability

Cavernoma	<p>Definition: <i>A cluster of abnormal blood vessels usually found in the brain or spinal cord.</i></p> <p>Grading source: CTCAEv4.03</p> <p>Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Cerebellar dysfunction	<p>Definition: A disorder characterized by lack of coordination of muscle movements resulting in the impairment or inability to perform voluntary activities. Includes: demyelization, drug-induced, hereditary, nutritional, surgical, trauma, tumors, or vascular causes.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Nervous system disorders: Ataxia</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate symptoms; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL; mechanical assistance indicated</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Cerebral necrosis	<p>Definition: A disorder characterized by a necrotic process occurring in the brain and/or spinal cord.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Nervous system disorders: Central nervous system necrosis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate symptoms; corticosteroids indicated</p> <p>3: Severe symptoms; medical intervention indicated (e.g., hyperbaric treatment of brain radiation necrosis)</p> <p>4: Life-threatening consequences; urgent/surgical intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Cerebrovascular accident	<p>Definition: A disorder characterized by a sudden loss of sensory function due to an intracranial vascular event. Includes: lacunes, hemorrhagic stroke, Ischemic stroke.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Nervous system disorders: Stroke</p>	<p>1: Asymptomatic or mild neurologic deficit; radiographic findings only</p> <p>2: Moderate neurologic deficit</p> <p>3: Severe neurologic deficit</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Cerebrovascular disease	<p>Definition: Includes: stenotic or occlusive large vessel disease, moyamoya.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Cranial nerve disorder	<p>Definition: A disorder characterized by involvement of a cranial nerve</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Nervous system disorders: Trigeminal, oculomotor, etc. Cranial nerve disorder</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate symptoms; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL (e.g., surgical intervention indicated)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Dysarthria	<p>Definition: A disorder characterized by slow and slurred speech resulting from an inability to coordinate the muscles used in speech.</p> <p>Grading source: St Jude modification of CTCAEv4.03</p> <p>Nervous system disorders: Dysarthria</p>	<p>1: Mild slurred speech (easily understood)</p> <p>2: Moderate impairment of articulation or slurred speech (some need for repetition to be understood)</p> <p>3: Severe impairment of articulation or slurred speech (unintelligible speech)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Generalized muscle weakness	<p>Definition: A disorder characterized by a reduction in the strength of muscles in multiple anatomic sites</p> <p>Grading source: ALL-STAR modification of CTCAEv4.03</p> <p>Musculoskeletal and connective tissue disorders</p>	<p>1: Symptomatic; weakness perceived by patient but not evident on physical exam</p> <p>2: Symptomatic; weakness evident on physical exam; weakness limiting instrumental ADL</p> <p>3: Weakness limiting self-care ADL; disabling; more than 2 SD below the expected mean (based on ALL-STAR control values)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Physical tests</p>

Headaches, chronic/ recurrent	<p>Definition: Includes: migraines Chronic headaches defined as headaches 15 days in a month for 3 consecutive months Recurrent headaches defined as at least 5 headaches over lifetime</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Headaches</p> <p>ALL-STAR modification: chronic/recurrent headache is defined as more than one episode per week. Migraine included as diagnose independent of frequency.</p>	<p>1: Mild pain 2: Moderate pain requiring prescriptive abortive medication; limiting instrumental ADL 3: Severe pain requiring prophylactic medication; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Hydrocephalus	<p>Definition: A disorder characterized by an abnormal increase of cerebrospinal fluid in the ventricles of the brain.</p> <p>Grading source: CTCAEv4.03 Nervous system disorders: Hydrocephalus</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Moderate symptoms; intervention not indicated 3: Severe symptoms or neurological deficit; intervention indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Hydrosyringomyelia	<p>Definition: - Includes: syrinx, syringohydromyelia, syringomyelia</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Intracranial hemorrhage	<p>Definition: A disorder characterized by bleeding from the cranium. Includes: subdural, subarachnoid, intraventricular.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Intracranial hemorrhage</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated (MRI evidence of microhemorrhage, e.g. hemosiderin) 2: Moderate symptoms; medical intervention indicated 3: Ventriculostomy, ICP monitoring, intraventricular thrombolysis, or operative intervention indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation

Movement disorders	<p>Definition: A disorder characterized by uncontrolled and purposeless movements. Includes: athetosis, ballism, chorea, dystonia, myoclonus, opsoclonus/ myoclonus, Parkinsonism, restless legs, tic tremor, torticollis.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Movements involuntary</p>	<p>1: Mild involuntary movements 2: Moderate involuntary movements; limiting instrumental ADL 3: Severe involuntary movements; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Multiple sclerosis	<p>Definition: An inflammatory disorder of the brain and spinal cord.³⁰</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Narcolepsy	<p>Definition: A disorder characterized by characterized by excessive sleepiness during the daytime</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Hypersomnia</p>	<p>1: Not applicable 2: Documentation of narcolepsy without need for therapy; moderate increased need for sleep 3: Documentation of narcolepsy with need for therapy; severe increased need for sleep 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Nerve root disorder	<p>Definition: A disorder characterized by inflammation involving a nerve root. Patients experience marked discomfort radiating along a nerve path because of spinal pressure on the connecting nerve root. Includes: radiculopathy, plexopathy, cauda equina syndrome.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Radiculitis</p>	<p>1: Mild symptoms 2: Moderate symptoms; limiting instrumental ADL; medical intervention indicated 3: Severe symptoms; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation

Neurogenic bladder	<p>Definition: Dysfunction of the lower urinary tract characterized by damage to the central nervous system (CNS), autonomic nervous system (ANS), or peripheral nervous system (PNS).³¹</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated (medical management e.g., oxybutynin); limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; surgical intervention indicated (e.g. ileal-anal pouch); disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire, COMPASS31, and medical record validation
Neurogenic bowel	<p>Definition: Dysfunction of the bowel characterized by damage to the central nervous system (CNS), autonomic nervous system (ANS), or peripheral nervous system (PNS).³²</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated (e.g. stool softener); limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; surgical intervention indicated (e.g. MACE); disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Neuromuscular disorders	<p>Definition: Includes: dermatomyositis, myotonia, neuromuscular disorder, polymyositis, rhabdomyolysis, steroid myopathy, critical illness myopathy/neuropathy</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Paralytic disorder	<p>Definition: Includes: hemiparesis/ plegia, quadriplegia/ plegia, paraparesis/ plegia, flaccid paralysis, spastic paralysis</p> <p>Grading source: St Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms (e.g., facial paraparesis); clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate (e.g., paraparesis); minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe weakness or sensory loss (e.g., paraplegia requiring wheelchair); limiting self-care ADL</p> <p>4: Life-threatening consequences (e.g., quadriplegia); urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Peripheral motor neuropathy	<p>Definition: A disorder characterized by inflammation or degeneration of the peripheral motor nerves. Includes: inflammatory demyelinating polyneuropathy disorder - Guillain-Barre syndrome.</p> <p>Grading source: CTCAEv4.03 Nervous system disorders: Peripheral motor neuropathy</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate symptoms; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL; assistive device indicated</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Neurological evaluation according to TNS including electroneurography.</p>
Peripheral sensory neuropathy	<p>Definition: A disorder characterized by inflammation or degeneration of the peripheral sensory nerves.</p> <p>Grading source: CTCAEv4.03 Nervous system disorders: Peripheral sensory neuropathy</p>	<p>1: Asymptomatic; loss of deep tendon reflexes or paresthesia</p> <p>2: Moderate symptoms; limiting instrumental ADL</p> <p>3: Severe symptoms; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Neurological evaluation according to TNS including electroneurography.</p>
Pseudomeningocele	<p>Definition: An accumulation of cerebrospinal fluid in the extradural space due to a fault in the dural arachnoid layer.³³</p> <p>Grading source: ST Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Pseudotumor cerebri	<p>Definition: A syndrome with increased intracranial pressure without a space-occupying lesion.³⁴</p> <p>Grading source: ST Jude modification of CTCAEv4.03 Nervous system disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical management or diagnostic observations only (e.g., weight control)</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL; medical intervention indicated or initiated (e.g., acetazolamide)</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL; surgical intervention indicated or initiated (e.g., lumbar puncture)</p> <p>4: Life-threatening consequences; urgent intervention indicated (e.g., severe visual impairment)</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>

Seizures	<p>Definition: A transient occurrence of signs and/or symptoms due to abnormal excessive or synchronous neuronal activity in the brain.³⁵</p> <p>Grading source: St Jude category and grading according to multidisciplinary team consensus</p>	<p>1: Seizures not requiring medication 2: Seizures requiring one non-prn medication 3: Seizures requiring two or more non-prn medications; poorly controlled seizures with prescribed medications 4: Seizures requiring evaluation for surgical intervention 5: Death</p>	- Questionnaire and medical record validation
OCULAR/VISUAL			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Cataract	<p>Definition: A disorder characterized by partial or complete opacity of the crystalline lens of one or both eyes. This results in a decrease in visual acuity and eventual blindness if untreated.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Cataract</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated (20/30 or better) 2: Symptomatic; moderate decrease in visual acuity (20/40 or better) 3: Symptomatic with marked decrease in visual acuity (worse than 20/40 but better than 20/200); operative intervention indicated (e.g., cataract surgery) 4: Blindness (20/200 or worse) in the affected eye 5: Not applicable</p>	- Questionnaire and medical record validation
Diplopia	<p>Definition: <i>Double vision</i></p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately sight threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Dry eye syndrome	<p>Definition: Includes: Keratitis sicca, xerophthalmia, kerato-conjunctivitis sicca, Sjogren's syndrome, lacrimal duct atrophy, limbal stem cell deficiency.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Other, specify</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; mild symptoms relieved by lubricants 2: Symptomatic; multiple agents indicated; limiting instrumental ADL 3: Decrease in visual acuity (<20/40); limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire, COMPASS31 and medical record validation

Eyelid function disorder	<p>Definition: Includes: entropion, ectropion, lagophthalmos, ptosis</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Other, specify</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; non-operative intervention indicated; limiting instrumental ADL</p> <p>3: Limiting self-care ADL; operative intervention indicated</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Glaucoma	<p>Definition: A disorder characterized by an increase in pressure in the eyeball due to obstruction of the aqueous humor outflow</p> <p>Grading source: CTCAEv4.03 Eye disorders: Glaucoma</p>	<p>1: Elevated intraocular pressure (EIOP) with single topical agent for intervention; no visual field deficit</p> <p>2: EIOP causing early visual field deficits; multiple topical or oral agents indicated; limiting instrumental ADL</p> <p>3: EIOP causing marked visual field deficits (e.g., involving both superior and inferior visual fields); operative intervention indicated; limiting self-care ADL</p> <p>4: Blindness (20/200 or worse) in the affected eye</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Ocular disease, noninfectious	<p>Definition: Includes: chorioretinitis, uveitis, iritis, scleritis</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately sight threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Sight-threatening consequences; urgent intervention indicated; blindness (20/200 or worse) in the affected eye</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Ocular surface disease	<p>Definition: A disorder characterized by inflammation to the cornea of the eye</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Keratitis</p>	<p>1: Not applicable</p> <p>2: Symptomatic; medical intervention indicated (e.g., topical agents); limiting instrumental ADL</p> <p>3: Decline in vision (worse than 20/40 but better than 20/200); limiting self-care ADL</p> <p>4: Perforation or blindness (20/200 or worse) in the affected eye</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Photophobia	<p>Definition: A disorder characterized by fear and avoidance of light.</p> <p>Grading source: CTCAEv4.03 Eye disorders: Photophobia</p>	<p>1: Symptomatic but not limiting ADL</p> <p>2: Limiting instrumental ADL</p> <p>3: Limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire, COMPASS31 and medical record validation

Phthisis bulbi	<p>Definition: Blind, painful eye</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders Eye pain</p>	<p>1: Mild pain 2: Moderate pain; limiting instrumental ADL 3: Severe pain; limiting self-care ADL 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Retinal detachment	<p>Definition: A disorder characterized by the separation of the inner retina layers from the underlying pigment epithelium.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Retinal detachment</p>	<p>1: Asymptomatic 2: Rhegmatogenous or exudative and visual acuity 20/40 or better 3: Rhegmatogenous or exudative detachment; operative intervention indicated; decline in vision (worse than 20/40 but better than 20/200) 4: Blindness (20/200 or worse) in the affected eye 5: Not applicable</p>	- Questionnaire and medical record validation
Retinopathy	<p>Definition: A disorder involving the retina.</p> <p>Grading source: CTCAEv4.03 Eye disorders: Retinopathy</p>	<p>1: Asymptomatic; clinical or diagnostic observations only 2: Symptomatic with moderate decrease in visual acuity (20/40 or better); limiting instrumental ADL 3: Symptomatic with marked decrease in visual acuity (worse than 20/40); disabling; limiting self-care ADL 4: Blindness (20/200 or worse) in the affected eye 5: Not applicable</p>	- Questionnaire and medical record validation
Strabismus	<p>Definition: Includes: esotropia, exotropia, hypertropia, Parinaud's syndrome, Internuclear ophthalmoplegia</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL 3: Severe or medically significant but not immediately sight threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Sight-threatening consequences; urgent intervention indicated; blindness (20/200 or worse) in the affected eye 5: Not applicable</p>	- Questionnaire and medical record validation
Visual acuity, reduced (OD)	<p>Definition: A disorder characterized by involvement of the optic nerve (second cranial nerve).</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Optic nerve disorder</p>	<p>1: Asymptomatic; clinical or diagnostic observations only (reduced visual acuity corrected to 20/40 or better) 2: Limiting vision of the affected eye (reduced visual acuity corrected to less than 20/40 but better than 20/60) 3: Limiting vision in the affected eye (reduced visual acuity corrected to 20/60 but better than 20/200) 4: Blindness (corrected to 20/200 or worse, includes count fingers, hand motion, light perception only) in the affected eye (cortical blindness, enucleation) 5: Not applicable</p>	- Questionnaire and medical record validation

Visual acuity, reduced (OS)	<p>Definition: A disorder characterized by involvement of the optic nerve (second cranial nerve).</p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Optic nerve disorder</p>	<p>1: Asymptomatic; clinical or diagnostic observations only (reduced visual acuity corrected to 20/40 or better)</p> <p>2: Limiting vision of the affected eye (reduced visual acuity corrected to less than 20/40 but better than 20/60)</p> <p>3: Limiting vision in the affected eye (reduced visual acuity corrected to 20/60 but better than 20/200)</p> <p>4: Blindness (corrected to 20/200 or worse, includes count fingers, hand motion, light perception only) in the affected eye (cortical blindness, enucleation)</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Visual field deficit	<p>Definition: <i>Partly or total loss of usual visual field.</i></p> <p>Grading source: St Jude modification of CTCAEv4.03 Eye disorders: Optic nerve disorder</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL (can't drive)</p> <p>3: Severe or medically significant but not immediately sight threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL (can't ambulate/navigate)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
PULMONARY			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Asthma	<p>Definition: A disorder characterized by a sudden contraction of the smooth muscles of the bronchial wall. Based on physician diagnosis by appropriate clinical signs and symptoms, <u>reversible</u> airway obstruction.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Bronchospasm</p>	<p>1: Mild symptoms; intervention not indicated</p> <p>2: Symptomatic; medical intervention indicated; limiting instrumental ADL; intermittent asthma requiring short-acting beta agonists as needed</p> <p>3: Limiting self-care ADL; oxygen saturation decreased; persistent asthma requiring daily controller medication (oral or inhaled)</p> <p>4: Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Lung function tests</p>

Chronic obstructive pulmonary disease (COPD)	<p>Definition: Based on physician diagnosis by appropriate clinical signs and symptoms, <u>irreversible</u> airway obstruction; includes emphysema, chronic bronchitis, and mixed chronic obstructive asthma/COPD syndrome.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated or initiated (inhaled medications); limiting age-appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life-threatening (e.g., requiring supplementation of oxygen, systemic corticosteroids, BIPAP, or CPAP); hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- Lung function tests</p>
Epistaxis, chronic/recurrent	<p>Definition: Defined as 3 events in last 6 months</p> <p>Grading Source: CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Epistaxis</p>	<p>1: Mild symptoms; intervention not indicated</p> <p>2: Moderate symptoms; medical intervention indicated (e.g., nasal packing, cauterization; topical vasoconstrictors)</p> <p>3: Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Obstructive sleep apnea	<p>Definition: A condition with narrowing or collapse of the throat causing repeatedly obstructive sleep apnoea events.³⁶</p> <p>Grading source: St Jude category and grading according to multidisciplinary team consensus</p>	<p>1: Documentation of apnea; no need for medication</p> <p>2: Documentation of mild apnea; behavioral intervention initiated or indicated</p> <p>3: Documentation of moderate apnea; CPAP initiated or indicated</p> <p>4: Documentation of severe apnea with secondary complications (CHF, HTN, headache)</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p>

Obstructive ventilatory defect	<p>Definition: Defined by FEV1 < 80% predicted and <LLN. Disorders associated with this pattern and <u>reduced</u> FEV1/FVC ratio (obstructive ventilatory defect) include: asthma, COPD, tracheobronchomalacia, obliterative bronchiolitis and bronchiectasis. Disorders associated with this pattern and normal or increased FEV1/FVC (possible restrictive ventilatory defect, confirm with TLC) include pulmonary fibrosis, other interstitial lung diseases, chest wall disorders)</p> <p>Grading source; New category and Grading source introduced by St Jude:</p> <p>Pellegrino et al, Interpretative strategies for lung function tests. Eur Resp J 2005;26:948-968. Table 6</p>	<p>1: FEV1 (percentages of observed FEV1 related to its predicted value): 79-70% predicted 2: FEV1: 69-50% predicted 3: FEV1: 49-35% predicted 4: FEV1: <35% predicted 5: Not applicable</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation - Lung function tests
Pleural space disorders	<p>Definition: Includes: pleural effusions, chylothorax, hemothorax</p> <p>Grading source: St Jude modification of CTCAEv4.03 Respiratory, thoracic and mediastinal disorders Pneumothorax</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate to severe symptoms and non-operative intervention indicated (e.g., tube placement without sclerosis) 3: Sclerosis and/or operative intervention indicated; hospitalization indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation
Pneumonitis	<p>Definition: A disorder characterized by inflammation focally or diffusely affecting the lung parenchyma.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Pneumonitis</p>	<p>1: Not applicable 2: Symptomatic; medical intervention indicated; limiting instrumental ADL 3: Severe symptoms; limiting self-care ADL; oxygen indicated 4: Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation) 5: Death</p>	<ul style="list-style-type: none"> - Questionnaire and medical record validation

Pulmonary diffusion defect	<p>Definition: DLCOcorr < 75% predicted and <LLN. Includes: pneumonitis, pulmonary fibrosis, other interstitial lung diseases, pulmonary vascular disorders and emphysema)</p> <p>Grading source: New category and Grading source introduced by St Jude:</p> <p>Pellegrino et al, Interpretative strategies for lung function tests. Eur Resp J 2005;26:948-968. Table 14</p>	<p>1: DLCO: 74-60% predicted 2: DLCO: <60%-40% predicted 3: DLCO: <40% predicted 4: Not applicable 5: Not applicable</p>	<p>- Questionnaire and medical record validation - Lung function tests</p>
Pulmonary embolism	<p>Definition: A disorder characterized by occlusion of a vessel by a thrombus that has migrated from a distal site via the blood stream.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Vascular disorders: Thromboembolic event</p>	<p>1: Not applicable 2: Not applicable 3: Urgent medical intervention indicated 4: Life-threatening with hemodynamic or neurologic instability 5: Death</p>	<p>- Questionnaire and medical record validation</p>
Respiratory tract hemorrhage	<p>Definition: A disorder characterized by bleeding from the bronchial wall and/or lung parenchyma.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Bronchopulmonary hemorrhage</p>	<p>1: Mild symptoms; intervention not Indicated 2: Moderate symptoms; medical intervention indicated 3: Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site) 4: Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation</p>

Restrictive ventilatory defect	<p>Definition: Defined by TLC < 75% predicted and <LLN. Includes: pulmonary fibrosis and other interstitial lung disease, pneumonitis, chest wall disorders.</p> <p>Grading source: New category and Grading source introduced by St Jude:</p> <p>American Thoracic Society, Lung Function Testing: Selection of Reference Values and Interpretative Strategies. Am Rev Respir Dis 1991;144:1202-1218. Table 13</p>	<p>1: TLC: 74 -70%</p> <p>2: TLC: 69 - 60% predicted; limiting instrumental ADL</p> <p>3: TLC: <60% predicted; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Lung function tests</p>
Tracheal aspiration	<p>Definition: A disorder characterized by inhalation of solids or liquids into the lungs.</p> <p>Grading source: ST Jude modification of CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Aspiration</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Altered eating habits; coughing or choking episodes after eating or swallowing; medical intervention indicated (e.g., suction or oxygen)</p> <p>3: Dyspnea and pneumonia symptoms (e.g., aspiration pneumonia); hospitalization indicated; unable to aliment orally</p> <p>4: Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>
Tracheal stenosis	<p>Definition: A disorder characterized by a narrowing of the trachea.</p> <p>Grading source: CTCAEv4.03 Respiratory, thoracic and mediastinal disorders: Tracheal stenosis</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic (e.g., noisy airway breathing), but causing no respiratory distress; medical management indicated (e.g., steroids)</p> <p>3: Stridor or respiratory distress limiting self-care ADL; endoscopic intervention indicated (e.g., stent, laser)</p> <p>4: Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>

PSYCHIATRIC			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Anxiety	<p>Definition: Validated patient reported outcome measure. Threshold of clinical intervention and impact on ADL</p> <p>Grading source: St Jude <i>"Detailed grading criteria for neuropsychological outcomes were outlined by psychologists incorporating patient-reported outcomes and the results of validated cognitive and psychological measures and comprehensive psychosocial evaluations by study social workers".¹</i></p> <p>ALL-STAR modification: Diagnosed by psychiatrist.</p>	<p>1: Score >1 SD above the mean and mental health intervention not indicated.</p> <p>2: Score >1.5 SD above the mean; Score ≤1.5 SD above the mean and treatment limited to 1 initiated or indicated mental health intervention; symptoms interfere with social or occupational functioning</p> <p>3: Score >2 SD above the mean; Score ≤2 SD and >1.5 SD above the mean and >1 mental health intervention initiated or indicated; symptoms interfere with self-care</p> <p>4: Hospitalization due to symptoms of anxiety indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Depression	<p>Definition: Validated patient reported outcome measure Threshold of clinical intervention and impact on ADL</p> <p>Grading source: St Jude <i>"Detailed grading criteria for neuropsychological outcomes were outlined by psychologists incorporating patient-reported outcomes and the results of validated cognitive and psychological measures and comprehensive psychosocial evaluations by study social workers".¹</i></p> <p>ALL-STAR modification: Diagnosed by psychiatrist.</p>	<p>1: Score >1 SD above the mean and mental health intervention not indicated</p> <p>2: Score >1.5 SD above the mean; Score ≤1.5 SD above the mean and treatment limited to 1 initiated or indicated mental health intervention; symptoms interfere with social or occupational functioning</p> <p>3: Score >1.5 above the mean and patient reports suicide ideation; Score >2 SD above the mean; Score ≤2 SD and >1.5 SD above the mean and >1 mental health intervention initiated or indicated; symptoms interfere with self-care</p> <p>4: Hospitalization due to symptoms of depression indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Other psychiatric disorders	<p>Definition A disorder characterized by personality change, impaired functioning, and loss of touch with reality. It may be a manifestation of schizophrenia, bipolar disorder or brain tumor. E.g., delirium; delusions; hallucinations; paranoia; psychosis</p> <p>Grading source: St Jude modification of CTCAEv4.03 Psychiatric: Psychosis</p> <p>ALL-STAR modification: Diagnosed by psychiatrist.</p>	<p>1: Mild symptoms reported, and mental health intervention not indicated 2: Moderate symptoms reported; treatment limited to 1 initiated or indicated mental health intervention; symptoms interfere with social or occupational functioning 3: Severe symptoms reported; >1 mental health intervention initiated or indicated; symptoms interfere with self-care 4: Hospitalization or urgent intervention due to symptoms is indicated 5: Death</p>	- Questionnaire and medical record validation
RENAL / URINARY			
Health condition	Definition and Grading source	Grading	ALL-STAR data
Acute kidney injury	<p>Definition: A disorder characterized by the acute loss of renal function and is traditionally classified as pre-renal (low blood flow into kidney), renal (kidney damage) and postrenal causes (ureteral or bladder outflow obstruction).</p> <p>Grading source: St Jude modification of CTCAEv4.03 Renal and urinary disorders: Acute kidney injury</p>	<p>1: Creatinine 1.5-2.0 x above age-specific ULN 2: Creatinine 2 - 3 x above age-specific ULN 3: Creatinine >3 x age-specific ULN or >4.0 mg/dL; hospitalization indicated 4: Life-threatening consequences; dialysis indicated 5: Death</p>	<p>- Questionnaire and medical record validation - Creatinine - Cystatin-C - eGFR</p>
Chronic hematuria	<p>Definition: A disorder characterized by laboratory test results that indicate blood in the urine. Defined as > 5 RBCs/hpf documented on more than one urinalysis.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Renal and urinary disorders: Hematuria</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated 2: Symptomatic; urinary catheter or bladder irrigation indicated; limiting instrumental ADL 3: Gross hematuria; transfusion, IV medications or hospitalization indicated; elective invasive intervention indicated; limiting self-care ADL 4: Life-threatening consequences; urgent invasive intervention indicated 5: Death</p>	- Questionnaire and medical record validation

Chronic kidney disease	<p>Definition: A disorder characterized by gradual and usually permanent loss of kidney function resulting in renal failure. Includes CKD requiring dialysis/transplant</p> <p>Grading source: St Jude modification of CTCAEv4.03 Renal and urinary disorders: Chronic kidney disease</p> <p>eGFR estimated used in the KDIGO estimating equations: http://www.kdigo.org/clinical_practice_guidelines/pdf/CKD/KDIGO_2012_CKD_GL.pdf</p> <p>ALL-STAR modification: eGFR estimated according to CKiDkrea-cysC-equation in children³⁷ and CKD-EPI_{crea}-equation in adults³⁸.</p>	<p>1: eGFR (estimated Glomerular Filtration Rate) or CrCl (creatinine clearance) <LLN – 60 ml/min/1.73 m² AND proteinuria 1+ present; urine protein/creatinine >0.5</p> <p>2: eGFR or CrCl 59-30 ml/min/1.73 m²; medication (e.g., electrolytes, ACE inhibition, etc....) indicated or initiated</p> <p>3: eGFR or CrCl 29-15 ml/min/1.73 m²</p> <p>4: eGFR or CrCl <15 ml/min/1.73 m²; dialysis or renal transplant indicated or initiated/performed</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p> <p>- eGFR</p>
Incontinence	<p>Definition: A disorder characterized by inability to control the flow of urine from the bladder.</p> <p>Grading source: CTCAEv4.03 Renal and urinary disorders: Urinary incontinence</p>	<p>1: Occasional (e.g., with coughing, sneezing, etc.), pads not indicated</p> <p>2: Spontaneous; pads indicated; limiting instrumental ADL</p> <p>3: Intervention indicated (e.g., clamp, collagen injections); operative intervention indicated; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p>
Obstructive uropathy	<p>Definition: A disorder characterized by blockage of the normal flow of contents of the urinary tract. Includes: urinary tract stenosis; urinary tract stricture.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Renal and urinary disorders: Urinary tract obstruction</p>	<p>1: Asymptomatic; clinical or diagnostic observations only</p> <p>2: Symptomatic but no hydronephrosis, sepsis or renal dysfunction; urethral dilation, urinary or suprapubic catheter indicated</p> <p>3: Symptomatic and altered organ function (e.g., hydronephrosis, or renal dysfunction); elective invasive intervention indicated</p> <p>4: Life-threatening consequences; urgent invasive intervention indicated</p> <p>5: Death</p>	<p>- Questionnaire and medical record validation</p>

Urinary bladder dysfunction	<p>Definition: A disorder characterized by a sudden compelling urge to urinate. Includes: dysfunctional voiding, hypertonic bladder, urinary frequency, urinary hesitancy.</p> <p>Grading source St Jude modification of CTCAEv4.03 Renal and urinary disorders: Urinary frequency Urinary urgency</p>	<p>1: Present 2: Limiting instrumental ADL; medical management indicated or initiated 3: Surgical management indicated or initiated (e.g., trans-electrical nerve stimulation, sacral neural modulation) 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation
Urinary tract calculi	<p>Definition: A disorder characterized by the formation of crystals in the pelvis of the kidney. Includes: renal calculi, bladder stone/calculi, ureteral calculi.</p> <p>Grading source: St Jude modification of CTCAEv4.03 Renal and urinary disorders: Renal calculi</p>	<p>1: Asymptomatic or mild symptoms; occasional use of nonprescription analgesics indicated 2: Symptomatic; oral antiemetics indicated; around the clock nonprescription analgesics or any oral narcotic analgesics indicated 3: Hospitalization indicated; IV intervention (e.g., analgesics, antiemetics); elective invasive intervention indicated 4: Life-threatening consequences; urgent invasive intervention indicated 5: Death</p>	- Questionnaire and medical record validation
Vesicoureteral reflux, acquired	<p>Definition: Abnormal retrograde flow of urine from the bladder to the ureter and potentially the kidney.³⁹</p> <p>Grading source: St Jude modification of CTCAEv4.03 Renal and urinary disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2: Moderate, local or noninvasive intervention indicated; limiting instrumental ADL 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	- Questionnaire and medical record validation
REPRODUCTIVE / GENITAL			
Health condition	Definition and Grading source	Grading	ALL-STAR data
<p>Abnormal sperm concentration</p> <p>(Includes: oligospermia, azospermia)</p>	<p>Definition: A disorder characterized by a decrease or complete absence of spermatozoa in the semen.</p> <p>St Jude modification of Reproductive system and breast disorders: Oligospermia Azoospermia</p>	<p>1: Not applicable 2: Sperm concentration > 0 but < 15 million spermatozoa/mL 3: Absence of sperm in ejaculate 4: Not applicable 5: Not applicable</p>	- Questionnaire and medical record validation

Cervical dysplasia	<p>Definition: Abnormal growth of cells on the surface of the cervix.⁴⁰</p> <p>Grading source: St Jude modification of CTCAE v4.03 Reproductive system and breast disorder: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL (e.g., colposcopy)</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL (e.g., conization for carcinoma-in-situ)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Dysfunctional uterine bleeding	<p>Definition: A disorder characterized by abnormally heavy vaginal bleeding during menses.</p> <p>Grading source: CTCAE v4.03 Reproductive system and breast disorders Menorrhagia</p>	<p>1: Mild; iron supplements indicated</p> <p>2: Moderate symptoms; medical intervention indicated (e.g., hormones)</p> <p>3: Severe; transfusion indicated; surgical intervention indicated (e.g., hysterectomy)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Endometriosis	<p>Definition: The presence of endometrial tissue outside the uterine cavity.⁴¹</p> <p>Grading source: St Jude modification of CTCAE v4.03 Reproductive system and breast disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL (e.g., medical management)</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL (e.g., surgical intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Erectile dysfunction	<p>Definition: A disorder characterized by the persistent or recurrent inability to achieve or to maintain an erection during sexual activity.</p> <p>Grading source: CTCAE v4.03 Reproductive system and breast disorders: Erectile dysfunction</p>	<p>1: Decrease in erectile function (frequency or rigidity of erections) but intervention not indicated (e.g., medication or use of mechanical device, penile pump)</p> <p>2: Decrease in erectile function (frequency/ rigidity of erections), erectile intervention indicated, (e.g., medication or mechanical devices such as penile pump)</p> <p>3: Decrease in erectile function (frequency/ rigidity of erections) but erectile intervention not helpful (e.g., medication or mechanical devices such as penile pump); placement of a permanent penile prosthesis indicated (not previously present)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	- Questionnaire and medical record validation
Genitourinary adhesions	<p>Definition: <i>Intraabdominal formation of fibrous bands between genital and urinary organs.</i></p> <p>Grading source: St Jude modification of CTCAE v4.03 Reproductive system and breast disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation

Hypogonadism, central (hypogonadotropic)	<p>Definition: A finding based on laboratory test results that indicate abnormal levels of gonadotrophin hormone in a blood specimen.</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Investigations: Blood gonadotropin abnormal</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; medical intervention indicated or initiated; limiting instrumental ADL</p> <p>3: Severe symptoms; medical intervention indicated or initiated; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- FSH</p> <p>- LH</p> <p>- Testosterone</p> <p>- SHBG</p>
Leydig cell insufficiency	<p>Definition: Leydig cell failure resulting from damage or loss of the machinery required for testosterone synthesis and release.⁴²</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Reproductive system and breast disorders: Other, specify</p>	<p>1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated</p> <p>2: Symptomatic; medical intervention indicated or initiated; limiting instrumental ADL</p> <p>3: Severe symptoms; medical intervention indicated or initiated; limiting self-care ADL</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- FSH</p> <p>- LH</p> <p>- Testosterone</p> <p>- SHBG</p>
Polycystic ovarian syndrome	<p>Definition: A clinical syndrome characterized by clinical or biochemical hyperandrogenism, oligo-anovulation, and polycystic ovarian morphology.⁴³</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Reproductive system and breast disorders: Other, specify</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated (e.g., mild signs/symptoms of hyperandrogenemia)</p> <p>2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL (e.g., more severe hirsutism, irregular menses; need for metformin or hormone replacement)</p> <p>3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL (e.g., need for surgery for cyst or bleed)</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p>
Precocious puberty	<p>Definition: A disorder characterized by unusually early development of secondary sexual features; the onset of sexual maturation begins usually before age 8 for girls and before age 9 for boys.</p> <p>Grading source: St Jude modification of CTCAE v4.03</p> <p>Endocrine disorders: Precocious puberty</p>	<p>1: Not applicable</p> <p>2: Physical signs and biochemical markers of puberty for females <8 years and males <9 years</p> <p>3: Not applicable</p> <p>4: Not applicable</p> <p>5: Not applicable</p>	<p>- Questionnaire and medical record validation</p> <p>- Tanner stage</p> <p>- Testicular volumes</p>

Primary ovarian failure	<p>Definition: A disorder characterized by ovarian failure before the age of 40. Symptoms include hot flashes, night sweats, mood swings and a decrease in sex drive.</p> <p>Grading source: CTCAE v4.03 Reproductive system and breast disorders: Premature menopause</p>	<p>1: Not applicable 2: Not applicable 3: Present 4: Not applicable 5: Not applicable</p>	<p>- Questionnaire and medical record validation - FSH - Estradiol</p>
Prostatic hypertrophy, benign	<p>Definition: A disorder characterized by compression of the urethra secondary to enlargement of the prostate gland. This results in voiding difficulties (straining to void, slow urine stream, and incomplete emptying of the bladder).</p> <p>Grading source: CTCAEv4.03 Reproductive system and breast disorders: Prostatic obstruction</p>	<p>1: Diagnostic observations only; intervention not indicated 2: Mild symptoms; elective intervention indicated 3: Severe symptoms; elective operative intervention indicated 4: Not applicable 5: Not applicable</p>	<p>- Questionnaire and medical record validation</p>
Vaginal fistula	<p>Definition: A disorder characterized by an abnormal communication between a female reproductive system organ and another organ or anatomic site.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Reproductive system and breast disorders: Female genital tract fistula</p>	<p>1: Asymptomatic clinical or diagnostic observations only; intervention not indicated 2: Symptomatic and intervention not indicated 3: Severe symptoms; elective operative intervention indicated 4: Life-threatening consequences; urgent intervention indicated 5: Death</p>	<p>- Questionnaire and medical record validation</p>
Vaginal stenosis	<p>Definition: A disorder characterized by a narrowing of the vaginal canal.</p> <p>Grading source: St Jude modification of CTCAE v4.03 Reproductive system and breast disorders: Vaginal stricture</p>	<p>1: Asymptomatic; mild vaginal shortening or narrowing 2: Vaginal narrowing and/or shortening not interfering with physical examination 3: Vaginal narrowing and/or shortening interfering with the use of tampons, sexual activity or physical examination (e.g., surgical intervention indicated or performed) 4: Not applicable 5: Not applicable</p>	<p>- Questionnaire and medical record validation</p>

NEOPLASMS			
Health condition	Definition and Grading source	Grading	- ALL-STAR data
Benign neoplasms	<p>Definition: Neoplasms benign, malignant and unspecified (incl cysts and polyps). Other, specify</p> <p>Grading Source ST Jude Modification of CTCAE v4.03 Neoplasms, benign, malignant</p>	<p>1: Low grade or benign neoplasms where surgical intervention is not indicated; observation or minimally invasive biopsy only (e.g. meningioma followed by MRI only or gastrointestinal polyps diagnosed and resected during colonoscopy)</p> <p>2: Any low-grade or benign neoplasm requiring surgical intervention more than a minimally invasive biopsy. Excludes CNS or cardiothoracic surgical interventions (e.g. fibroadenomas, thyroid adenomas, gastrointestinal polyps requiring surgical resection)</p> <p>3: Any low-grade or benign neoplasm requiring CNS or cardiothoracic surgical intervention (e.g. meningioma or myxoma requiring intervention)</p> <p>4: Life-threatening consequences; urgent intervention indicated</p> <p>5: Death</p>	- Questionnaire and medical record validation
Malignant neoplasms	<p>Definition: Neoplasms benign, malignant and unspecified (incl cysts and polyps). Other, specify</p> <p>Grading Source ST Jude Modification of CTCAE v4.03 Neoplasms, benign, malignant</p>	<p>1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; low-grade neoplasms where intervention is not indicated (e.g. cervical dysplasia/CIN and teratoma incidentally identified on imaging)</p> <p>2: Moderate symptoms; minimal, local, or noninvasive intervention indicated; limiting age appropriate instrumental ADL; low-grade, non-metastatic neoplasms (e.g. cervical carcinoma <i>in situ</i>, cervical lymph node paraganglioma, basal cell carcinoma, squamous cell carcinoma, parotid carcinoma)</p> <p>3: Severe or medically significant, but not immediately life-threatening; hospitalization indicated; disabling; limiting self-care ADL; high-grade neoplasms where single-treatment therapy required (surgery, radiation with or without chemotherapeutic agent; e.g. breast cancer if <i>in situ</i>, prostate cancer, meningioma requiring intervention, bladder carcinoma, thyroid cancer, carcinoid, squamous cell carcinoma cervix, glioma, astrocytoma, gastrointestinal stromal tumor)</p> <p>4: Life-threatening consequences; urgent intervention indicated; high-grade neoplasms where multimodal therapy required or more than one chemotherapy agent used (e.g. MDS, AML, ALL, Hodgkin lymphoma, non-Hodgkin lymphoma, non-<i>in situ</i>/invasive breast cancer, osteosarcoma, Ewing sarcoma, primitive neuroectodermal tumor, soft tissue sarcoma, renal cancer, anaplastic CNS Tumor, glioblastoma, carcinoma of head/neck, liver cancer, lung cancer, mesothelioma, melanoma)</p> <p>5: Death</p>	-

Table 1 references

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